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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/147,912 11/03/93 WAHL

G P419498

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EXAMINER

HM12/0828

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ART UNIT

PAPER NUMBER

1653

DATE MAILED:

08/28/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	08/147,912	WAHL ET AL.
	Examiner	Art Unit
	Christopher S. F. Low	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to ~~communication(s) filed on paper 40, the remand of 30 Aug 2000~~.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 25,26,28,42-46 and 48 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 25,26,28,42-46 and 48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) Interview Summary (PTO-413) Paper No(s). 41.
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

This application has been remanded from the United States Patent And Trademark Office Board Of Patent Appeals And Interferences (hereinafter the Board). Prosecution is reopened.

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- Discussions were held on or about 17 October 2000 and on or about the week of 19 March 2001 regarding double patenting and considerations of amending the claims in light of the discussion by the Board as to claim language.
 - The amendment after final filed 20 July 1995 (17 July 1995 U. S. Postal Service certification date) has been entered. Claims 25, 26, 42, 44, and 48 have been amended.
 - The following grounds of objection and/or rejection are applied to pending claims 25, 26, 28, 42-46, and 48.

10 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Actiond.

Double Patenting

15 The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

20 A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome actual or provisional rejection(s) based on non-statutory double patenting ground(s) of rejection set forth below provided the conflicting application(s) or patent(s) is/are shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25 Claims 25, 28, 42-46 and 48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-18 of U.S. Patent No. 5,677,177. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the present application, the method is directed to precisely targeting a DNA into the genome by stable integration of the DNA at an FRT site using the FLP recombinase whereas in the '177 patent, the use of alternative terminology "assembly of function genes" using an FRT site and FLP recombinase are obvious variation because it would have been obvious that the gene was for expression in the cell (recited in the '177 patent claims) and/or for affecting expression of another gene.

Claims 25, 28, 42-46 and 48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5,654,182. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the present application, the method is directed to precisely targeting a DNA into the genome by stable integration of the DNA at an FRT site using the FLP recombinase whereas in the '182 patent, the use of alternative terminology "assembly of function genes" using an FRT site and FLP recombinase are obvious variations because the gene was for expression in the cell (recited in the '177 patent claims) and/or for affecting expression of another gene.

Claims 25 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 5,885,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the present application, the method is directed to precisely targeting and excising a DNA into the genome by stable integration of the DNA at an FRT site using the FLP recombinase whereas in the '836 patent, the claims are directed as in the present application, to excising a polynucleotide (claim 1+ of '836 patent). Thus, the claims are an obvious variation.

112 Second Paragraph

As to the rejection of claims 25, 26, 28, 42-46 and 48 under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The comments in the remand by the Board have been considered. The rejection is withdrawn.

Obviousness Rejection

Claims 25, 26, 28, 42-46, and 48 stand rejected under 35 U.S.C. 103 as being unpatentable over Golic *et al.* (1989) Cell 59: 499-509 taken with Rogers *et al.* (1987) WO 87/03006 (newly cited) and Palmiter *et al.* (1986) Ann. Rev. Genet. 465-499.

Golic *et al.* disclose site specific recombination in *D. melanogaster* with DNA coding for FLP and FRT (see at least pages 499 and 507) where it is indicated that FRT bearing plasmids can be directed to the site of an FRT already resident in the genome suggesting its use for germline transformation which would have resulted in a transgenic animal and further indicate that "we expect it will work in other organisms as well" which would have motivated one of ordinary skill in the art to combine the teachings with that of the Rogers *et al.* which at page 2C teaches one of ordinary skill in the art that "this invention also encompasses a method of and vector system for the regulated

expression of heterologous genes in yeast, bacteria, and higher eucaryotic cells such as plant and mammalian cells", thus, it would have been obvious to one of ordinary skill in the art to have put the vectors from either Golic *et al.* and/or Rogers *et al.* in mammalian cells.

Where Golic *et al.* indicate expectation of success as indicated above, one of ordinary skill in
5 the art would have found it obvious to combine the teachings in the Palmiter *et al.* reference which discloses introduction of the transforming DNA into totipotent teratocarcinoma cells or embryonic stem cells which can be introduced into the developing embryo by aggregation of the cells. Here, where Rogers *et al.* and Golic *et al.* disclose the plasmids with the FLP and FRT DNA for site specific recombination, it would have been obvious to one of ordinary skill in the art given that Golic *et al.*
10 indicate that "we expect that it will work in other organisms as well", to modify the process by using totipotent teratocarcinoma cells or embryonic stem cells as disclosed by Palmiter *et al.* which are later aggregated with the developing mouse embryo. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

15 No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Low whose telephone number is (703) 308-2923. Inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone
20 number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1) and must conform to the notice published in the Official Gazette, 1096 OG 30 (15 November 1989). The telephone number assigned to Art Unit 1653 in the CM1 PTO Fax Center is (703) 308-4242.

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CSFL
26 Aug 2001



CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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John J. Doll, Director
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